DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
NA-35

60 8th Street, N.E.
Atlanta, Georgia 30309

June 15, 2000

VIA FEDERAL EXPRESS

Jim Barrazza
President
Auxi Health, Inc.
810 Crescent Centre Drive
Suite 260
Franklin, Tennessee 37067

WARNING LETTER
(00-ATL-48)

Dear Mr. Barrazza:

An inspection of your medical oxygen transfilling facility, Procare Home Health Care Services, Inc., located in Douglas, Georgia, was conducted between May 25 and June 1, 2000, by Investigator B. Douglas Brogden. Our investigator documented several significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code Of Federal Regulations (21 CFR), Part 211. These deviations cause your transfilled drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

You have failed to formally establish and designate a quality control unit to handle critical functions such as the review of daily production records and release of transfilled lots for distribution. No written procedures were available which addressed the responsibilities and functions of the quality control unit at your firm.

You failed to ensure that each person responsible for supervising the manufacture, processing, packing, or holding of your drug product had the education, training, and experience, or any combination thereof, to perform their assigned functions in such a manner as to provide assurance that the drug had the safety, identity, strength, quality, and purity that it purports to possess. There was no documentation available of any training of the individual responsible for reviewing and approving all batch production records. There was no evidence that he had completed any of the basic training requirements for your filling operators described in Procare's procedures.

You have failed to properly calibrate your [redacted] analyzer used for the assay of Oxygen USP, in that you did not have the high purity nitrogen standard required to calibrate the "zero" on the meter. Your firm was using an outdated procedure that allowed the use of room air for calibration.

You have failed to conduct an appropriate laboratory determination of satisfactory conformance to final specifications for the drug product prior to release. No odor test is performed as part of the post filling operations prior to release. The procedures on file did not require such a test.

Batch records did not always accurately reflect the actual filling operations that had occurred. Portions of batch records were not recorded contemporaneously with the action being performed. An example, observed during the inspection, was the transfilling of cylinders on 5/25 which were reportedly evacuated on 5/23. There was no indication of any filling activities from 5/23 on the batch record prepared.

You failed to follow filling procedures on file at the firm when cylinders were evacuated. It was observed on 5/25 that a filling yoke was disconnected from one of the cylinders during the evacuation process prior to filling. This would break the vacuum created and introduce a potential source of adulteration. This was described as a routine practice.

At the conclusion of the inspection, our investigator issued his Inspectional Observations (FDA 483) to, and discussed the findings with, James McElhaney, Medical Equipment & Oxygen Technician. A copy of the FDA 483 is enclosed for your review. Additional reference materials were provided to assist your firm in complying with the law. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all-inclusive list of violations that may be in existence at your facility. It is your responsibility to ensure that all requirements of the Act are met at this and any other similar facility under your authority.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office within fifteen (15) working days of receipt of this letter of all steps you have taken, or intend to take, to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed with 15 working days, state the reason for the delay and the time within which corrections will be completed. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

Roger E. Kline

Ballard H. Graham, Director
Atlanta District